IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

YARY PACHECO, ***Plaintiff,*** **v.** **JOHNSON & JOHNSON, *et al.*,** ***Defendants.***	**CIVIL ACTION NO.** **3:24-cv-00002-TES**

ORDER GRANTING IN PART AND DENYING IN PART
DEFENDANTS' MOTION TO DISMISS

Before the Court is Defendants Johnson & Johnson and Ethicon, Inc.'s Partial Motion to Dismiss [Doc. 25], requesting that the Court consolidate several of Plaintiff's claims and limit her suit to a few causes of action. Right now, Plaintiff's Amended Complaint alleges six causes of action: (1) negligence in "the design, manufacture, testing, inspection, processing, advertising, marketing, labeling, assembling, packaging, distribution, detailing, promotion and sale of the Product"; (2) design defect based on a theory of strict liability; (3) manufacturing defect based on a theory of strict liability; (4) inadequate warning based on a theory of strict liability; (5) breach of express warranty; and (6) gross negligence, also in "the design, manufacture, testing, inspection, processing, advertising, marketing, labeling,

assembling, packaging, distribution, detailing, promotion and sale of the Product."[1] [Doc. 24, pp. 13, 21, 23, 25, 28, 34].

Defendants' request is a little tricky and requires much explanation, but in the simplest terms possible for purposes of this brief introduction, Defendants essentially request that the Court limit Plaintiff's product defect claims to design defect and failure-to-warn (now Counts II and IV), and consolidate her claims for negligence and gross negligence (now Counts I and IV) into the design-defect and failure-to-warn claims (which the Amended Complaint pleads under only a theory of strict liability), thus allowing her to pursue those two claims under strict liability, negligence, and gross negligence theories.[2] [Doc. 25-1, pp. 9–10]. The Court agrees in part and disagrees in part, as it will explain further below.

BACKGROUND[3]

To treat her stress urinary incontinence ("SUI"), Plaintiff underwent a surgery

[1] Under her claim for gross negligence (Count VI), Plaintiff reincorporates the paragraphs from her negligence claim (Count I). [Doc. 24, ¶ 157]. Therefore, her gross negligence claim is based on the same actions or inactions as her negligence claim—e.g., errors in the design, manufacture, testing, and inspection, among others. *See* [*id.*]; [Doc. 24, ¶ 55].

[2] Additionally, in their Motion to Dismiss, Defendants originally asked the Court to dismiss Plaintiff's breach of express warranty claim as untimely, but after Plaintiff responded, Defendants withdrew (at this stage in the proceedings only) that argument and consented to the claim going forward for now. [Doc. 25-1, pp. 12–13]; [Doc. 28, p. 1]. Therefore, Plaintiff's breach of express warranty claim will proceed for further factual development.

[3] The following facts are taken from Plaintiff's Complaint [Doc. 1] and are assumed to be true for the purpose of ruling on the Motion before the Court. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (holding that when ruling on a 12(b)(6) motion, courts must accept the facts set forth in the complaint as true).

on June 18, 2010, in which her doctor, Dr. Mark Adams, implanted with the Product at issue, a TVT-O pelvic mesh product "designed, manufactured, packaged, labeled, and sold by Defendants" and was marketed as a permanent implant for long-term use within the human body. [Doc. 24, ¶¶ 19–21, 40–41, 100, 128, 140]. The surgery went off without a hitch, with no intraoperative complications and remained in Plaintiff's body for many years. [*Id*. at ¶ 42]. But then, on March 8, 2022, Plaintiff came to Oconee Surgery Center in Watkinsville, Georgia, complaining of vaginal pain, dyspareunia (pain with sex), frequent urinary tract infections, difficulty urinating, and pelvic pain, and that same day, underwent a revision surgery, in which Dr. Brian Raybon surgically removed as much of the TVT-O sling material as possible. [*Id*. at ¶¶ 44–45]. He was unable to remove all of the mesh. [*Id*. at ¶ 49].

In that surgery, Dr. Raybon found evidence of an old infection/abscess and significant scarring near the sling and also noticed that the sling was rolled into a tubular structure. [*Id*. at ¶¶ 46, 49]. Plaintiff continues to suffer vaginal pain, dyspareunia, frequent urinary tract infections, difficulty urinating, pelvic pain, mesh erosion, and exposed mesh. [*Id*. at ¶ 47]. She alleges that although she has undergone one correction surgery, she will likely need another, as well as further treatments. [*Id*. at ¶ 47].

Plaintiff alleges multiple defects and notes that it is "impossible to isolate a single defect as the cause, as these defects work in conjunction with one another to

cause injuries to users." [*Id*. at ¶ 48]. However, the results of the explant surgery helped Plaintiff identify some defects, including the use of polypropylene material (a material prone to causing injuries), the tendency of the mesh to contract and deform once inside the body, its inelasticity, and its propensity to degrade over time. [*Id*. at ¶ 49].

Despite these defects and risks, Plaintiff alleges that Defendants marketed the product as safe (describing it in a brochure provided to Plaintiff as a minimally invasive procedure involving a "soft, flexible mesh"), withheld information from the medical community and general public, and failed to conduct tests ensuring the Product's safety. [*Id*. at ¶¶ 49, 74, 76–77, 135–138, 141]. Had Plaintiff and Dr. Adams known of the risks, Dr. Adams would not have recommended the Product, and/or Plaintiff would not have consented to it. [*Id*. at ¶¶ 49, 68–69].

LEGAL STANDARD

When ruling on a Rule 12(b)(6) motion to dismiss for failure to state a claim, it is a cardinal rule that district courts must accept the factual allegations set forth in a complaint as true. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007). In accepting the factual allegations as true, courts are to construe the reasonable inferences from them in the light most favorable to the plaintiff. *Hawthorne v. Mac Adjustment, Inc.*, 140 F.3d 1367, 1370 (11th Cir. 1998).

However, through Rule 12(b)(6), a defendant may "test the facial sufficiency" of

a complaint by way of a motion to dismiss. *Ghee v. Comcast Cable Commc'ns, LLC*, No. 22-12867, 2023 WL 3813503, at *2 (11th Cir. June 5, 2023) (quoting *Brooks v. Blue Cross & Blue Shield*, 116 F.3d 1364, 1368 (11th Cir. 1997)). Such a "motion is an 'assertion by a defendant that, even if the facts alleged by a plaintiff are true, the complaint still fails as a matter of law to state a claim upon which relief may be granted.'" *Barreth v. Reyes 1, Inc.*, No. 5:19-cv-00320-TES, 2020 WL 4370137, at *2 (M.D. Ga. July 29, 2020) (citation omitted). A complaint survives a Rule 12(b)(6)-based motion only if it alleges sufficient factual matter (accepted as true) that states a claim for relief that is plausible on its face. *McCullough*, 907 F.3d at 1333 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009)).

Now, whether a complaint states a claim for relief is measured by reference to the pleading standard of Federal Rule of Civil Procedure 8—a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Barreth*, 2020 WL 4370137, at *2 (citation omitted). Rule 8 doesn't require detailed factual allegations, but it does require "more than unadorned, the-defendant-unlawfully-harmed-me accusations." *McCullough*, 907 F.3d at 1333 (citation omitted) (alterations adopted). Its sole purpose is to provide a defendant "with 'fair notice' of the claims and the 'grounds' for entitlement to relief." *Barreth*, 2020 WL 4370137, at *2 (citation omitted); *Twombly*, 550 U.S. at 555–56.

Courts use a two-step framework to decide whether a complaint survives a motion to dismiss. *McCullough*, 907 F.3d at 1333 (citation omitted). The first step is to

identify the allegations that are "no more than conclusions." *Id.* (quoting *Iqbal*, 556 U.S. at 679). "Conclusory allegations are not entitled to the assumption of truth." *Id.* After disregarding the conclusory allegations, the second step is to "assume any remaining factual allegations are true and determine whether those factual allegations 'plausibly give rise to an entitlement to relief.'" *Id.* "A court decides whether [Rule 8's pleading standard] is met by separating the legal conclusions from the factual allegations, assuming the truth of only the factual allegations, and then determining whether those allegations allow the court to reasonably infer that [a] plaintiff is entitled to the legal remedy sought." *Barreth*, 2020 WL 4370137, at *2 (citation omitted).

When drafting a complaint, "[a] plaintiff must plead more than labels and conclusions or a formulaic recitation of the elements of a cause of action." *McCullough*, 907 F.3d at 1333 (quoting *Twombly*, 550 U.S. at 555). A plaintiff may use legal conclusions to structure a complaint, but they "must be supported by factual allegations." *McCullough*, 907 F.3d at 1333 (quoting *Iqbal*, 556 U.S. at 679). While courts, in ruling on a motion to dismiss, must take all of the factual allegations in a complaint as true, they are not bound to accept a legal conclusion couched as a factual allegation. *Iqbal*, 556 U.S. at 678. Courts must "identify conclusory allegations and then discard them—not 'on the ground that they are unrealistic or nonsensical' but because their conclusory nature 'disentitles them to the presumption of truth.'" *McCullough*, 907 F.3d at 1333 (quoting *Iqbal*, 556 U.S. at 681).

The issue to be decided when considering a motion to dismiss "is necessarily a limited one." *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974) *overruled on other grounds by Davis v. Scheuer*, 468 U.S. 183 (1984). The issue is not whether the claimant will ultimately prevail, but "whether the claimant is entitled to offer evidence to support the claims." *Id.* The factual allegations in a complaint "must be enough to raise a right to relief above the speculative level" and cannot "merely create[] a suspicion of a legally cognizable right of action." *Twombly*, 550 U.S. at 555. Finally, and in this case, critically, a complaint that tenders "'naked assertions' devoid of 'further factual enhancement'" will not survive against a motion to dismiss. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557) (cleaned up). To survive, a complaint must allege enough facts "to raise a reasonable expectation that discovery will reveal evidence" supporting a claim. *Twombly*, 550 U.S. at 556.

DISCUSSION

Defendants ask the Court to limit the scope of Plaintiff's negligence and gross negligence claims to three types: design defect, manufacturing defect, and warning/marketing defect. [Doc. 25-1, pp. 9–12]. Then, they argue that the Court should consolidate those negligence and gross negligence claims (Counts I and VI) into Plaintiff's strict-liability claims for design defect (Count II), manufacturing defect (Count III), and inadequate warning (Count IV). [*Id.*]. Finally, Defendants argue that Plaintiff fails to state a claim for manufacturing defect. [*Id.*]. The end result, if

Defendants got their way, would be that Plaintiff has only two product defect claims (design defect and warning/marketing defect) that she can each pursue on three different theories (negligence, gross negligence, and strict liability). *See* [*id*.]. The Court will address each step of Defendants' argument in turn.

1. Limitation of Negligence and Gross Negligence Claims

Defendants first argue that the Court should limit Plaintiff's "general negligence" claims to the "three recognized" products liability claims: manufacturing defects, design defects, and marketing/packaging defects (also known as "inadequate warning" or "failure-to-warn"). [Doc. 25-1, p. 9 (citing *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 672 (Ga. 1994))]. Specifically, Plaintiff's negligence and gross negligence claims are based on allegedly inadequate "design, manufacture, testing, inspection, processing, advertising, marketing, labeling, assembling, packaging, distribution, detailing, promotion and sale of the Product." [Doc. 24, ¶¶ 55, 157]. According to Defendants, all of those types of product defects are each simply a species within one of the three main categories. [Doc. 25-1, pp. 9–10]; [Doc. 24, ¶¶ 55, 157]. In other words, the first question before the Court is whether Plaintiff can base her negligence claims on types of defects *beyond* those three main categories—or whether those various other defects are subsumed *within* the three recognized categories.

Various district courts have found the latter. *See, e.g.*, *Schulze v. Ethicon, Inc.*, No. 1:22-CV-26-DAK-JCB, 2023 WL 2914381, at *2–3 (D. Utah Apr. 12, 2023); *Dupere v.*

Ethicon, Inc., No. 21-CV-2605-DLC, 2022 WL 523604, at *3–4 (S.D.N.Y. Feb. 22, 2022); *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989).[4] In one case very similar to the one at bar involving the same Defendants, the court found that New York law did not recognize an independent theory based on a failure to test, and it also noted that "the Third Restatement of Torts defines only three activities creating product liability: liability for a manufacturing defect due to a defect in design, the manufacturing process, or in a failure to warn." *Dupere*, 2022 WL 523604, at *3–4 (citing Restatement (Third) of Torts: Prod. Liab. § 2 (1998)). The court also recognized that the American Jurisprudence treatise explicitly adopts the Restatement's formulation and describes a products liability action as addressing "a defect in a product" that consists of "a mistake in manufacturing, improper design, or the inadequacy or absence of warnings regarding the use of the product." *Id*. (citing 63 Am. Jur. 2d Products Liability § 10 (2022)). The District of Utah followed the exact same reasoning and landed at the same conclusion in a similar case. *See Schulze*, 2023 WL 2914381, at *2–3.

[4] Defendants cite a case in which the Northern District of Georgia, in a footnote, accepted the defendant's argument that the plaintiff's "negligent research and testing claim [was] really a failure-to-warn claim in disguise" because the plaintiff failed to oppose the argument in a responsive brief. *Swinney v. Mylan Pharms, Inc.*, No. 4:22-CV-90-MLB, 2023 WL 2090702, at *2 n.3 (N.D. Ga. Feb. 17, 2023); [Doc. 25-1, pp. 10–11].

Additionally, Defendants cite a Sixth Circuit case on a motion for summary judgment in which the court noted that the plaintiff's failure-to-test claim "collapse[d] into [his] failure-to-warn claim." *Rodgriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012); [Doc. 25-1, pp. 10–11].

Notably, however, these courts do not seem to hold that plaintiffs cannot allege (or ultimately establish) that a defendant failed to test a product; rather, they simply hold that any allegation of failure-to-test is a sub-part of one of the three main claims. *Kociemba*, 707 F. Supp. at 1527 ("The duty to test is a subpart of the other three duties because a breach of the duty to test cannot by itself cause any injury."). In other words, just because "negligent testing," for example, is not an independent cause of action, "evidence of a testing regimen or its absence may be submitted in connection with a particular claim, for instance to defend against or support a claim of negligence in product design." *Dupere*, 2022 WL 523604, at *4. This is because "unless the manufacturer's breach of its duty to test leads the manufacturer to produce a product that is defective in design, manufacture, or warning, no injury can result." *Kociemba*, 707 F. Supp. at 1527. "If the manufacturer designs the product safely, manufactures the product safely, and provides an adequate warning of dangers inherent in the use of the product, then a failure to test the product cannot, standing alone, cause any injury." *Id.*; *see Bergman*, 2021 WL 5028418, at *5.

All that to say, as "Georgia does not recognize a cause of action for negligent testing" and Georgia courts also recognize manufacturing defects, design defects, and warning defects as the "three general categories of product defects," the Court is inclined to agree with Defendant that the other types of defects are simply species of the three main categories, rather than causes of action in and of themselves. *See*

Villegas v. Deere & Co., 135 F. App'x 279, 281 (11th Cir. 2005); *Banks*, 450 S.E.2d at 672; [Doc. 25-1, pp. 9–10]. To the extent that Plaintiff attempts to assert an independent cause of action on the grounds of testing, inspection, or any other activity outside of the three recognized categories, those claims fail as a matter of law.

Before further complicating things with the consolidation issue, that means Plaintiff—at this point in the Court's analysis—has three negligence and gross negligence claims: (1) manufacturing, (2) design, and (3) marketing/warning. She does not have, for example, a negligent testing claim that stands by itself. *See Kociemba*, 707 F. Supp. at 1527. That said, if this case proceeds to trial, Plaintiff certainly may present evidence that Defendants failed to adequately test the Product in order to prove that they were negligent or grossly negligent in the manufacturing, design, or warnings/marketing of the Product.[5] *See* [Doc. 25-1, p. 11]; [Doc. 24, ¶¶ 55, 157]; *Schulze*, 2023 WL 2914381, at *3 (noting that "Plaintiff may offer evidence related to these theories"); *Dupere*, 2022 WL 523604, at *4 (also noting that "evidence of a testing regimen or its absence may be submitted in connection with a particular

[5] To the extent Defendants are arguing that Plaintiff may not use evidence of, for example, an inadequate testing regime to prove her three main claims at trial, Defendants are incorrect. *See* [Doc. 25-1, p. 11 ([E]ven if Plaintiff could pursue any extraneous theories of negligence outside of the three recognized theories, her Complaint does not allege facts that would plausibly support those theories.")]. Plaintiff is not required to allege every fact that may be uncovered in discovery. That would be an impossible burden. Plaintiff must only allege sufficient facts entitling her to relief—and Defendants do not dispute that she has stated a claim for design defect and inadequate warning. *See Twombly*, 550 U.S. at 570. See *generally* [Doc. 25-1]. Even if her Amended Complaint had not mentioned testing or inspection at all, that would not prohibit her from bringing evidence at trial—uncovered during discovery—of Defendants' inadequate testing or inspection regime.

claim").

2. Consolidation of Negligence, Gross Negligence, and Strict-Liability Claims

Now it's time to complicate things even more. Defendants next point out that Plaintiff pleads her manufacturing defect, design defect, and warning defect claims under strict-liability theories as independent causes of action in Counts II through IV but then seems to base her negligence and gross negligence claims in Counts I and VI on those same grounds. [*Id.*]; *see* [Doc. 24, ¶¶ 55, 157]. Essentially, Defendants believe that—after limiting her negligence and gross negligence claims to the "three recognized" types—her negligence and gross negligence claims should then be consolidated into her strict-liability claims. *See* [Doc. 25, pp. 9–10, 12]. Thus, Plaintiff would have three[6] product defect claims (manufacturing defect, design defect, and inadequate warning) that she can pursue on three theories (negligence, gross negligence, and strict liability).

The Court agrees that this is the best course of action—but only for Plaintiff's negligent design-defect claim and strict-liability design-defect claim. *See Schmidt v. C.R. Bard, Inc.*, No. 6:14-CV-62, 2014 WL 5149175, at *6 (S.D. Ga. Oct. 14, 2014) (consolidating the plaintiff's design-defect negligence claim and design-defect strict-liability claim into a single count); *see also* Restatement (Third) of Torts: Products

[6] That is, at this point in our analysis. Defendants also contend that the Court should dismiss Plaintiff's manufacturing-defect claims for failure to state a claim, as the Court will explain in the next section of this Order. *See infra* Part B.

Liability, § 2 cmt. n ("To allow two or more factually identical risk-utility claims to go to a jury under different labels, whether 'strict liability,' 'negligence,' or 'implied warranty of merchantability,' would generate confusion and may well result in inconsistent verdicts."); *Cessna v. Ethicon, Inc.*, No. 7:20-CV-37-WLS, 2020 WL 2121392, at *10 (M.D. Ga. Apr. 2, 2020) ("Defendants' contention that the negligent-design-defect claim is duplicative of Count V is arguably one for dismissal rather than summary judgment and is more appropriately raised in a motion for partial dismissal.").

Defendants attempt to cite several cases in which courts consolidated negligent and strict-liability design-defect claims to support its argument that Plaintiff's inadequate-warning and manufacturing-defect claims should be consolidated too. *See* [Doc. 25-1, pp. 9–10 (citing cases)]. However, to do that would be to ignore the reason courts merge design-defect claims.[7]

"Although 'no precise test has been articulated' for determining whether a claim in one action is duplicative of a claim in another action, the Eleventh Circuit has stated that the 'general rule' is that claims are duplicative if the 'parties, issues and available relief do not significantly differ.'" *Cessna*, 2020 WL 2121392, at *7 (quoting *I.A. Durbin, Inc. v. Jefferson Nat. Bank*, 793 F.2d 1541, 1551 (11th Cir. 1986)). When

[7] Additionally, it would also ignore that other courts—including in at least one case involving the same Defendants—do not consolidate failure-to-warn and manufacturing-defect claims. *See, e.g.*, *May v. Ethicon, Inc.*, No. 1:20-cv-322-TWT, 2020 WL 674357, at *3 (N.D. Ga. Feb. 11, 2020).

analyzing strict-liability design-defect claims, Georgia courts utilize the risk-utility analysis, which "incorporates the concept of 'reasonableness.'" *See, e.g.*, *Banks*, 450 S.E.2d at 673; *Ogletree v. Navistar Int'l Transp. Corp.*, 522 S.E.2d 467, 469 (Ga. 1999) ("[T]he mandate that a product's risk must be weighed against its utility incorporates the concept of 'reasonableness,' so as to apply negligence principles in the determination of whether the manufacturer defectively designed its product."); *see also Grieco v. Tecumseh Prod. Co.*, No. 4:12-CV-195, 2013 WL 5755436, at *4 (S.D. Ga. Oct. 23, 2013) ("For design defects, courts ask whether a defendant failed to adopt a reasonable alternative design which would have reduced the foreseeable risks of harm presented by the product.") (citing *Jones v. NordicTrack, Inc.*, 550 S.E.2d 101, 103 (Ga. 2001)). Thus, because negligence claims also obviously inherently involve an element of reasonableness, "only semantics distinguishes the [design-defect] cause of action for negligence and a cause of action pursuant to O.C.G.A. § 51-1-11 (claiming strict liability for defective design)." *Banks*, 450 S.E.2d at 674 n.3[8]; *see also NordicTrack*, 550 S.E.2d at 103 n.5 ("This Court has recognized that there is no significant

[8] Plaintiff correctly points out that in *Banks*, the Georgia Supreme Court did not mandate consolidation of design-defect cases in "every conceivable factual scenario." 450 S.E.2d at 674 n.3. However, since the *Banks* decision in 1994, most courts consolidate strict-liability design-defect claims and negligent design-defect claims. *See Schmidt v. C.R. Bard, Inc.*, No. 6:14-CV-62, 2014 WL 5149175, at *6 (S.D. Ga. Oct. 14, 2014) ("With regard to [the plaintiff's] negligence claims predicated on alleged design defects, both negligence and design defect 'claims use the same risk-utility analysis, and therefore will be treated as one claim.'"). All that said, this "decision in no way narrows the scope of the issues to be litigated at trial." *May v. Ethicon, Inc.*, No. 1:20-cv-322-TWT, 2020 WL 674357, at *3 (N.D. Ga. Feb. 11, 2020).

distinction between negligence and strict liability for purposes of the risk-utility analysis.").

The same reasonableness analysis, however, does not apply to Plaintiff's gross negligence design-defect claim—nor any of her manufacturing-defect and inadequate-warning claims. First, Defendants cite no authority to support their contention that the Court should consolidate Plaintiff's now-singular negligent and strict-liability design-defect claim with her gross negligence design-defect claim. *See* [Doc. 25-1, p. 12]. In fact, Defendants point out that gross negligence involves a "higher degree of culpability" than ordinary negligence. [*Id*. (quoting *Montgomery v. PNC Bank, N.A.*, No. 1:12-CV-0265-AT-JSA, 2014 WL 11531623, at *9 (N.D. Ga. July 21, 2014), *report & recommendation adopted as modified sub nom.* 2014 WL 11531624 (N.D. Ga. Aug. 22, 2014))]. The Georgia Code "defines gross negligence as the absence of 'slight diligence,' characterized as the 'degree of care which every man of common sense, however inattentive he may be, exercises under the same or similar circumstances.'" *Williams v. Ethicon, Inc.*, No. 1:20-CV-04341-SDG, 2021 WL 857747, at *4 (N.D. Ga. Mar. 8, 2021) (quoting O.C.G.A. § 51-1-4). Unlike the resemblance between the elements required to prove negligent design defect and strict-liability design defect, a "gross negligence claim contains separate elements—and requires different proof—than [a] simple negligence claim." *See id*. In other words, the two claims are not duplicative. *Cessna*, 2020 WL 2121392, at *7.

In a case against the same Defendants as here, Defendants made the same argument to the Northern District of Georgia that they are now making to this Court: namely that the court should merge plaintiff's claims for negligence and gross negligence premised on alleged design defects should be merged with his strict-liability design-defect claim. *Williams*, 2021 WL 857747, at *3. The Northern District agreed with their argument as to strict liability and negligence but rejected their argument as to gross negligence. *Id*. at *4 (explaining that plaintiff's gross negligence claim "raises a different issue" than his "claims for negligence and strict liability with regard to a design defect"). Unlike ordinary negligence, gross negligence "is an independent cause of action under Georgia law." *Id*. (citing O.C.G.A. § 51-1-4); *see Jones v. Ethicon, Inc.*, No. 7:20-CV-128 (HL), 2020 WL 5836555 (M.D. Ga. Sept. 30, 2020) ("Defendants have not otherwise explained why Plaintiff's gross negligence claim cannot be separately pleaded nor why the Court should prevent a jury from determining whether Plaintiff can satisfy the elevated gross negligence standard."). Therefore, Plaintiff will have two design-defect claims: (1) negligent and strict-liability design defect and (2) grossly negligent design defect.

Additionally, Plaintiff's manufacturing-defect and inadequate-warning claims may not be consolidated at all. They will proceed separately as negligent, grossly negligent, and strict-liability claims. In other words, a negligent failure-to-warn claim is not duplicative of a strict-liability failure-to-warn claim. *Bryant v. Hoffman-La Roche,*

Inc., 585 S.E.2d 723, 730 n.6 (Ga. Ct. App. 2003) ("A claim for negligent failure to warn exists separately from strict liability claims."); *see also Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999) (recognizing that a negligent failure to warn claim may be brought concomitantly with the analogous strict-liability claim). Nor is it duplicative of a grossly negligent failure-to-warn claim. *See Williams*, 2021 WL 857747, at *4. The same goes for a manufacturing-defect claim. *May*, 2020 WL 674357, at *3 ("Count I of the Master Complaint also contains claims for negligent manufacturing defect and negligent failure to warn. These claims are distinct from, and can be brought concomitantly with, analogous claims sounding in strict liability."). Plaintiff's gross negligence claim will remain separate from all of her negligence and strict-liability claims.

3. <u>Manufacturing Defect</u>

Finally, Defendants argue that the Court should dismiss Plaintiff's manufacturing-defect claims for failure to state a claim, arguing that her allegations, particularly in Paragraph 97 of her Amended Complaint, are insufficient and/or conclusory.[9] [Doc. 25-1, pp. 4–7]. In Response to Defendants' Motion, Plaintiff argues

[9] Specifically, Defendants contend that Plaintiff's allegation that Defendants used "non-medical grade mesh material" [Doc. 24, ¶ 102] does not support how their manufacturing process deviated from an objective standard or from Defendants' own specifications. [Doc. 25-1, p. 4]. Her allegation of "mesh which degrades" [Doc. 24, ¶ 102] also doesn't support that the degradation is a deviation, according to Defendants. [Doc. 25-1, p. 5]. On the contrary, Plaintiff contends this very same flaw is a design defect in another paragraph of the Amended Complaint. *See* [Doc. 24, ¶ 35 ("The design defect of the TVT-O, including . . . degradation)], *in connection with* [*id*. at ¶ 85 (incorporating Paragraph 35 as design defects)]. Finally, Defendants contend that Plaintiff's allegation "mesh which was not cut according to

that her Amended Complaint did not need to specify the manner of the defect precisely because a manufacturing defect can be inferred from circumstantial evidence and because she needs discovery to obtain that kind of specificity. [Doc. 27, p. 6–8]. The Court agrees with Defendants on this one.

To allege a manufacturing defect, Plaintiff must allege the existence of a specific manufacturing defect that caused her harm. *Henderson v. Sun Pharms. Indus.*, Ltd., No. 4:11-CV-0060-HLM, 2011 WL 4024656, at *5 (N.D. Ga. June 9, 2011). In contrast to a design-defect claim, a manufacturing defect is one where the flaw occurred in the manufacturing process, not in the design or specifications of the product. *See Fletcher v. Water Applications Distribution Grp.*, 773 S.E.2d 859, 863 (Ga. Ct. App. 2015). Rather than being an unreasonable design used to create all copies of the manufactured product, a manufacturing defect is "a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product." *Jones v. Amazing Prod., Inc.*, 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002). "Therefore, in a manufacturing defect case, the 'product's defectiveness is determined by measuring the product in question against the benchmark of the manufacturer's designs.'" *In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010) (quoting *ACE Fire Underwriters Ins. Co. v. ALC Controls, Inc.*, No. 1:07-CV-606-T, 2008 WL 2229121, at *2 (N.D. Ga. May 28,

specifications" [Doc. 24, ¶ 102] is vague and conclusory. [Doc. 25-1, pp. 6–7].

2008)).

In Response to Defendants, Plaintiff cites *Wilson v. Synthes USA Products, LLC*, in which the district court held that although some of the plaintiff's allegations were "not extremely specific," the complaint, read as a whole, supported a claim for relief. 116 F. Supp. 3d 463, 468 (E.D. Pa. 2015). There, to support a manufacturing-defect claim, the plaintiff had pled that her spinal implant fractured, which the plaintiff's brief called "a plain departure from the intended design." Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss, *Wilson*, 116 F. Supp. 3d 463, 2014 WL 11279430. However, unlike our Plaintiff, the *Wilson* plaintiff had also alleged facts about a government agency determining that the Defendants had poor manufacturing standards at their plant. *See id*.; *see generally* [Doc. 24].

In the case at bar, Plaintiff maintains that her Amended Complaint states a claim for manufacturing defect because it "alleges that her TVT-O device deviated from Defendants' intended result/design and deviated from seemingly identical models." [Doc. 27, p. 8 (citing [Doc. 24, ¶ 97])]. However, the Amended Complaint is not even that specific. Granted, Paragraph 97 states that her device "deviated materially from Defendants' design and manufacturing specifications," and Paragraphs 102 and 103 list ways in which the Product was allegedly defective, including that it "shrinks, contracts, and deforms" and contains "contaminants in the mesh" and "degradation." [Doc. 24, ¶¶ 97, 102–03]. But even assuming all these

allegations are true, there are no facts in the Amended Complaint supporting the bare legal assertion that they were "deviat[ions] . . . from Defendants' design and manufacturing specifications." *See* [*id*. at ¶ 97]. That is simply a regurgitation of the essential element of a manufacturing-defect claim.

Because Plaintiff has "not alleged any facts regarding [the Product's] intended design or specifications, how its manufacture deviated from those specifications, or how such a deviation caused the alleged injuries," she has not stated a claim for manufacturing defect. *Langston v. Ethicon Inc.*, No. 3:20-CV-3712-S, 2021 WL 6198218, at *5 (N.D. Tex. Dec. 31, 2021). Consequently, she cannot base her negligence or gross negligence claims on a manufacturing defect, and her independent manufacturing-defect claim based on strict liability also fails.

CONCLUSION

Accordingly, the Court **GRANTS in part** Defendants' Motion [Doc. 25], **DISMISSING** Plaintiff's manufacturing-defect claims and **CONSOLIDATING** her negligent design defect and strict-liability design defect into a single count. As Defendants withdrew (at this stage in the proceedings only) their initial argument Plaintiff's breach of express warranty was untimely, that claim will also proceed to further factual development. *See* [Doc. 25-1, pp. 12–13]; [Doc. 28, p. 1]. In sum, Plaintiff is left with the following claims: (1) negligence claim based on failure-to-warn; (2) design defect based on both strict liability and negligence; (3) failure-to-

warn based on strict liability; (4) breach of express warranty; and (5) gross negligence based on inadequate warning and design defect. She may pursue evidence in discovery as to inadequate testing and any of the other manners of negligence listed in Paragraphs 55 and 157 of her Amended Complaint.

SO ORDERED, this 1st day of July, 2024.

S/ Tilman E. Self, III
TILMAN E. SELF, III, JUDGE
UNITED STATES DISTRICT COURT